

Update on the ACIP Combination Vaccines Working Group (WG)

Patricia Stinchfield, RN, MS, CPNP
ACIP Combination Vaccines WG Chair,
Director, Pediatric Infectious Disease & Immunology
Infection Control, Children's Hospitals and Clinics of
Minnesota

ACIP WG Members

ACIP chair: Patsy Stinchfield

ACIP members: Susan M. Lett

CDC co-leads: Angela Calugar and M. Patricia Joyce

▪ **CDC Staff:**

- Jim Alexander – DVD/NCIRD
- Tom Clark – DBD/NCIRD
- Andrew Kroger – ISD/NCIRD
- Nancy R. Messonnier – DBD/NCIRD
- Amy Parker – DVD/NCIRD
- Larry Pickering – CCID/NCIRD
- Jean C. Smith – CCID/NCIRD
- Sandra Steiner – CCID/NCIRD
- Greg Wallace – ISD/NCIRD

▪ **ACIP liaison and other members**

- Jonathan L. Temte – AAFP
- Jay Butler – AKA IHS
- Jeff Davis – WI DOH
- Shelley Deeks – Public Health Agency of Canada
- Jeffrey S. Duchin – NACCHO
- Sarah Long – COID/AAP
- Karen M. Farizo – FDA
- Theresa Finn – FDA

ACIP Combination Vaccines Working Group

Terms of Reference

- **Short-term goal**
 - Review the vaccine Pentacel® (DTaP-IPV-Hib) in anticipation of discussion at one of the future ACIP meetings, pending FDA licensure.
- **Long-term goal**
 - Review issues surrounding the availability and use of combination vaccines.
 - Develop a revised statement on use of Combination Vaccines for review and approval by ACIP, to replace the 1999 MMWR statement.

Pentacel®

Background Information

- Sanofi pasteur submitted a Biological License Application (BLA) for 4-dose primary series in children 2, 4, 6, and 15-18 months
- FDA requested additional information from Sanofi pasteur, which resulted in an extension of the review clock for this BLA.
- Pentacel® was approved in Canada in 1996 and in all jurisdictions by 1997-1998

Topics Covered by the WG

Re: Pentacel®, April-June 2007

- Overview based on VRBPAC presentations
- Immunogenicity of the vaccine's components
- Canadian Experience with Pentacel®
- Feedback from American Academy of Pediatrics, including Committee Of Infectious Diseases
 - Harmonization of the future recommendations and agreement with the Red Book
 - Program implementation in special populations i.e. American Indian/Alaskan Native children
 - Pentacel® in the Childhood Immunization Schedule

Future Topics to be Addressed by the WG Pentacel®

- Pending FDA approval
 - Detailed presentation at the October 2007 ACIP meeting on the Pentacel®-related topics
 - Continue working on the draft MMWR communication (Notice to Readers) and presenting it for discussion at the February 2008 ACIP meeting
 - ACIP vote on inclusion of Pentacel® in the VFC Program (three VFC resolutions) in February-2008.

Future Topics to be Addressed by the WG Other Combination Vaccines

- Review and prepare to communicate to the ACIP on other combination vaccines new to the US market
 - FDA has accepted for review GlaxoSmithKline (GSK) BLA for the new DTaP-IPV pediatric booster vaccine for immunization against diphtheria, tetanus, pertussis, and polio diseases in children 4 through 6 years of age (Personal communication with GSK, 06-18-07)

Future Topics to be Addressed by the WG

MMWR Statement on Combination Vaccines

- Update the 1999 MMWR statement on use of Combination Vaccines
 - Review issues surrounding the availability and use of combination vaccines in the U.S. market
 - Develop a revised statement, to replace the 1999 MMWR statement, on use of Combination Vaccines for discussion and approval by ACIP
 - Decide whether to incorporate the Combination Vaccines topic into the General Recommendations document